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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,113

09/18/2006

Gil Naor

P-70415-US

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EXAMINER

BLATT, ERIC D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

10/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,113	Applicant(s) NAOR ET AL.	
	Examiner Eric Blatt	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9-8-2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-26 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1 and 14 recite, "an outer surface facing the upstream side of the main blood vessel." This recitation positively claims a portion of a human body, namely, a portion of a main blood vessel.

Claims 4 and 17 also positively claim the main blood vessel

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 14 functionally recite the main vessel and branch vessel throughout the majority of the claims, but then positively recite "the upstream side of the main blood vessel" as discussed above. This contradiction renders the claims indefinite. Examiner

suggests amending this portion of the claim language to recite, "including an outer surface configured to face the upstream side of the main blood vessel." For present purposes of examination, claims 1 and 14 will be interpreted as such.

Claims 4 and 17 also positively claim the main blood vessel contradictory the rest of the claim language. Examiner suggests amending this portion of the claim language to recite, "said diverter section is of decreasing width along a direction of the device configured to extend towards the center of center of said main passageway when the device is implanted in the branch passageway." For present purposes of examination, claims 4 and 17 will be interpreted as such.

Claims 9 and 22 seem to positively recite that the device is positioned in a human anatomy. Examiner suggests amending this portion of the claim language to recite, "said diverter of the open braid cylinder is angled away from the anchoring section of the open braid cylinder in the downstream direction of fluid flow when the device is implanted in a branched lumen." For present purposes of examination, claims 9 and 22 will be interpreted as such.

Claims 12 and 25 recite that the diverter section is of a width smaller than the diameter of the main blood vessel. Different patients and different anatomies will have differing main blood vessel diameters. Since no particular main blood vessel is claimed, the diameter of the main blood vessel is not defined, and the claim is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26, as understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Marotta et al. (US 6,676,696) in view of Yassour et al. (US 6,348,063)

Marotta discloses an implant device (Figure 5) for implantation in the body of a subject to divert solid particles in body fluid flowing through a main passage way of the subject from entering a branch passageway downstream of the main passageway. The implant device comprises two tubular anchoring sections and a diverter section including an outer surface. The first anchoring section is capable of firmly anchoring the implant device in the branch passageway, the diverter section is capable of projecting into the main passageway such that it permits fluid flow through the main passageway, and the outer surface is capable of facing the upstream side of the main passageway effective to divert solid particles in the body fluid from entering the branch passageway.

The device of Marotta is designed for blocking fluid flow into an aneurysm and as such, the diverter section is not porous to allow fluid flow therethrough. (Paragraph 13) Yassour teaches a structurally similar device having a porous diverter section and teaches that the device may be useful for deflecting emboli from traveling from a main vessel lumen into a branch vessel lumen. It would have been obvious to modify the

apparatus of Marotta by providing the diverter section with a plurality of openings therethrough such that it may be used for deflecting emboli from traveling from a main vessel lumen into a branch vessel lumen as taught by Yassour.

The outer surface of the diverter section is of a convex configuration so as to reduce turbulence of the blood flow through said main passageway. (Figure 6) The diverter section is of decreasing width along a direction of the device configured to extend towards the center of center of said main passageway when the device is implanted in the branch passageway. (Figure 10) The diverter section, modified as taught by Yassour, is in the form of a curved planar sheet perforated with a plurality of openings therethrough. The anchoring section and the diverter section are formed of an open braided material. (Paragraphs 12 and 13) The diverter section is of bulbous configuration (Figure 8) integrally formed with said anchoring section, and includes an opening at the downstream side communicating with the interior of the anchoring section. One end of the open braid cylinder constitutes said anchoring section for anchoring in the branch passageway, and the opposite end of said open braid cylinder constitutes said diverter section for projecting into said main passageway. Said diverter section of the open braid cylinder is angled away from the anchoring section and is capable of being angled in the downstream direction of fluid flow.

Marotta does not disclose that the open braid material is formed of strands of at least two different diameters. Yassour discloses that the anchoring section may be formed of strands having a first diameter while the diverter section is formed having a second different diameter. (Column 8, Lines 15-19) It would have been obvious to one

Art Unit: 3734

of ordinary skill in the art at the time of the invention to modify the apparatus of Marotta by forming the diverter section from strands having a different diameter than those of the anchoring section in order to better filter emboli as taught by Yassour.

Marotta does not disclose that the device is constructed and dimensioned for implantation in the aorta artery such that the anchoring section is to be anchored in the carotid artery and the diverter section is to project into the aorta lumen. Yassour discloses that such devices may be useful for treatment of aortic conditions. (Column 8, Lines 62-67) It would have been obvious to one of ordinary skill in the art at the time of the invention to size the device of Moratta for implantation in the carotid and aortic arteries in order to treat said anatomies.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 3734

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

Eric Blatt
571-272-9735